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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,945	08/04/2003	Michael S. Tyndall	KOM 4295	5207

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,945	TYNDALL ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/6/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *36-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/4/05; 11/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the Restriction Requirement dated June 6, 2005 Applicant elected with traverse Group I, claims 1-35 for continued examination.

Claims 12-16 and 36-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species as well as nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 6, 2005.

2. Applicant's election with traverse of Group I claims 1-35 is acknowledged. The traversal is on the ground that the claims should be examined together because claim 1 and 36 were intentionally drafted to closely mirror each other and to capture the same inventive concepts. Thus, the burden of examining the additional claims having overlapping search fields cannot fairly be said to be "serious". This argument has been considered, but is not found persuasive. Claims 1-35 are directed to a composition and claims 36-51 are directed to a method of treating and/or preventing. These are different statutory classes of invention and MPEP § 806.05(f) states that these inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. In the case at hand the examiner has averred that the product as claimed can be used in a different way. The examiner has further established a primae facie case of a burden by establishing a different classification for these two different statutory groups of invention.

Applicants note that their process claims include all the limitations of their product claims. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The use of multiple trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating bovine mastitis comprising a phospholipd-containing skin conditioner and an antimicrobial agent, does not reasonably provide enablement for a composition for the treatment or prevention of

any infection in any and all animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Iodine is a bluish-black mineral that is a part of thyroxin, which regulates basal metabolism. While iodine can be used for a plurality of things, iodine's most common use is to disinfect external wounds. The instant specification teaches the use of iodine as an antimicrobial agent (page 10) for treatment of mastitis.

The Wands factors have been considered in the establishment of this instant scope of enablement rejection:

a. the quantity of experimentation necessary would be undue for the utilization of any amount of any antimicrobial agent administered to any animal for the prevention or treatment of any infection;

b. the amount of direction or guidance presented is not disclosed;

c. the presence or absence of working examples utilizing antimicrobial agents capable of treating or preventing any infection in any animal other than mastitis in a cow with iodine as the antimicrobial agent have not been provided;

d. the nature of the invention is one that without specific guidance, would result in a method that would not successfully treat or prevent an infection in said animal;

e. the state of the prior art is one in which specifically sites, the uses of iodine as being (1) an element found in disinfectants, (2) an element found in salts, (3) an element required in humans and (4) an element in liquid form used to put on open wounds (Uses of Iodine,

http://www.pleasantridge.k12.ca.us/magnolia/elements/iodine/iodine2.html). Moreover, well known animal infections like rabies, West Nile disease or Foot-and-Mouth Disease cannot be prevented with the use of iodine and/or antimicrobial agents. While you can use iodine to disinfect the wound in the case of rabies, treatment consist of a one-time injection of human rabies immune globulin and a series of vaccine doses to provide protection against rabies after an exposure (Rabies, Medicine Consumer Health, 2003; pages 1-8, http://www.eMedicine.com);

f. the relative skill of those in the art: high;

g. the predictability or unpredictability of the art: unpredictable; and

h. breadth of the claims: broad.

In view of the prior art teaching (references cited above and specific teachings of the instant specification) the topical veterinary composition for the treatment or prevention of any infection in any animal comprising an anti-microbial agent and a phospholipid-containing skin conditioner would not predictably result in the positive desired effect. The instantly claimed invention is enabled only for a scope as defined above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

5. Claims 6 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 6 and 31, Formula II incorrectly recites a

generic formula wherein the secondary amine has a positive charge yet no other bonds or functional groups are shown to indicate how the secondary amine could be charged; missing covalent bonds or functional groups, low pH, etc. In addition, in claims 6 and 31, Formula II recites limitation in the formula "where X + Y = 3, or mixtures thereof." It is not understood what is mixed; a small permutation of X and Y, or the resulting compounds that arise from different compounds of Formula II with different X and Y values.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Beerse et al (US 6,258,368 B1).

Claims 1 and 3 are drawn to a topical veterinary composition for the treatment or prevention of infection in animals comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Beerse et al discloses an antimicrobial cleansing composition that contains antimicrobial agents (list of agents located in columns 6-9). Beerse et al discloses a wide variety of lipid type materials and mixtures of materials that are suitable for use in an antimicrobial composition. Moreover, Beerse et al disclose the lipophilic skin-conditioning agent is selected from a group comprising phospholipids and mixtures thereof (column 14, lines 42-62 and column 15, lines 10-11). Lastly, Beerse et al disclose the lipophilic skin moisturizing agent are employed at the level of about 0.1% to about 30% (column 14, lines 46-51). Claim limitations such as "for the treatment or prevention of infection in animals" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458. Limitations such as the composition comprising between about 0.01 and about 20-wt % are being viewed as limitations of optimizing experimental parameters.

7. Claims 1-4, 17, 28, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Khan et al (US 5,824,359).

Claims 1-4, 17, 28, 29 and 30 are drawn to drawn to a topical veterinary composition for the treatment or prevention of infection in animals comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Khan et al disclose the use of lecithin (phospholipid) as a lubricant (column 3, lines 23-25). Khan et al discloses that the composition should be between about 0.5% and about 10.0% by weight of lecithin (column 3, lines 40-43). Khan et al discloses that examples of anti-microbial agents that may be used in the solution include idophors among others (column 4, lines 20-26). Moreover, Khan et al discloses that the preferably weight is between about 1% and about 5% by weight of the antimicrobial agent. Lastly, Khan et al disclose that the solution can also include other ingredients such as surfactants and vitamin E (column 3, lines 41-45). OneLook defines the term iodophor as a combination of iodine with a surfactant carrier. Preparations generally contain 1% iodine, which is released to take affect against microorganisms; used as skin disinfectants. Thus the examiner is viewing iodophor as the iodine antimicrobial agent. Claim limitations such as "for the treatment or prevention of infection in animals" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458. Limitations such as the composition

comprising between about 0.01 and about 20-wt % are being viewed as limitations of optimizing experimental parameters.

8. Claims 1,3, 7, 17, 24, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Jampani et al (WO 01/41727 A1).

Claims 1,3, 7, 17, 24, 28 and 29 are drawn to a topical veterinary composition for the treatment or prevention of infection in animals comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Jampani et al discloses antimicrobial agents in effective amounts from about 0.01 to about 5.0 (page 18, lines 1, 9-11). Jampani et el discloses hydrophilic oil skin conditioners that are useful in the invention as being linoleamidopropyl phosphatidyl PG-dimonium chloride (Phospholipid EFA- Uniquema) and coco phosphatidyl PG-dimonium chloride (Phospholipid CDM, Uniquema) among others (page 12, lines 5-10). Jampani et el also discloses an effective amount of the above skin conditioners as about 0.1 to about 5.0 (page 12, lines 13-17). Additionally, Jampani et al disclose surfactants that are useful in the invention (page 14, lines 10-19). Moreover, Jampani et al disclose useful thickeners for the invention (page 12, lines 20-30). Lastly, Jampani et al disclose that Vitamin E is one of the useful additives in making the formulations of this invention (page 23, lines 24-25). Claim limitations such as "for the treatment or prevention of infection in animals" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458. Limitations such as the composition comprising between about 0.01 and about 20-wt % are being viewed as limitations of optimizing experimental parameters.

9. Claims 1, 17, 24 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayne et al (US 6,881,427 B2).

Claims 1, 17, 24 and 28 are drawn to a topical veterinary composition for the treatment or prevention of infection in animals comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Mayne et al disclose compositions that may contain various known and conventional cosmetic ingredients which include but are not limited to carriers, diluents, emollients, emulsifiers, surfactants, thickening agents, vitamins, skin conditioners, moisturizers, phospholipids, antimicrobial agents and the like ad well as combinations thereof (column 4, lines 54-67 and column 5, lines 1-10). Claim limitations such as "for the treatment or prevention of infection in animals" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a

process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

10. Claim Claims 1,2,30 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hei et al (US 6,436,445 B1).

Claims 1,2,30 and 32-35 are drawn to a topical veterinary composition for the treatment or prevention of infection in animals comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Hei et al discloses examples of liquid compositions comprising lecithin (phospholipid), mineral oil (emollient) iodine (antimicrobial agent) and water (columns 21 and 22). Claim limitations such as "for the treatment or prevention of infection in animals" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458. Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference

between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hahn et al (US 2003/0031727 A1) discloses topical product formulations for reducing skin irritation.

Modak et al (US 2004/0102429 A1) discloses compositions for the prevention of dermal and mucosal irritation.

Jansen et al (Review Article, Bovine Encephalopathy and foot-and-mouth disease, two animal epidemics transferable to humans CEJOEM, 2001; 7(3-4): 155-67) discloses treament for Bovine Spongiform Encephalopathy and foot-and-mouth disease.

Klofta et al (US 2003/0077307 A1) disclose compositions for protecting the skin.

Holzner et al (U.S. 5,420,104) disclose compositions for protecting the skin.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

NITA MINNIFIELD
PRIMARY EXAMINER
8/22/05